UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

July 27, 2007

MEMORANDUM:

Subject: Occupational and Residential Exposure and Risk Assessments for the New Wood Preservative Use of Kathon 287 (4,5 Dichloro-2-octyl-2H-isothiazol-3-one)

To: Marshall Swindell, Product Manager
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DP Barcodes: 330114 and 340329

Chemical No.: 128101

Chemical Name: 4,5 Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT)

1.0. Action Requested

The Antimicrobial Division's (AD) Regulatory Management Branch I has requested that Risk Assessment and Science Support Branch (RASSB) conduct exposure and risk assessments to support Rhom and Haas Company's application for the registration of a new end use product of 4,5 Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT). DCOIT is the active ingredient in Kathon 287 which is intended to be used as a pressure treated wood preservative.

2.0. Summary of Findings

Based on the use patterns for the proposed new use of DCOIT, RASSB concludes that the Margins of Exposure (MOEs) for the following inhalation ***occupational*** screening-level scenarios exceed the Agency's level of concern (i.e., less than the target MOE of 30):

- ST/IT Inhalation exposure for pressure treatment workers involved in TO job functions at the maximum application rate: MOE = 24
- ST/IT Inhalation exposure for pressure treatment workers involved in TA job function at the maximum application rate: MOE = 28
- ST/IT Inhalation exposure for pressure treatment workers involved in PK job function at the maximum application rate: MOE = 21

The following construction worker risks could be refined by using a bioavailability factor from a leaching study that is conducted on saw dust rather than wood cubes as submitted by the registrant, Rhom and Haas.

- ST/IT Inhalation exposure for construction workers (total wood dust) handling wood treated at the maximum and minimum application rates: MOE < 1
- ST/IT Inhalation exposure for construction workers (respirable wood dust) handling wood treated at the maximum and minimum application rates: MOE < 1

None of the long-term dermal occupational MOEs exceeded the Agency's level of concern (i.e., MOE > target MOE of 300). It should be noted that short-and intermediate-term dermal exposures were not assessed for the occupational handler because the endpoint is based on dermal sensitization. Instead, dermal sensitization exposures need to be mitigated using personal protective equipment requirements. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed during application will be a long-sleeve shirt, long pants, shoes, socks and chemical-resistant gloves. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential.

Although none of the ST dermal or incidental oral exposures are of concern for the ***residential*** post-application scenario of DCOIT using the currently available data, RASSB believes that the residential post-application exposures may be underestimated

due to the uncertainties and limitations of the dislodgeable residue studies. The major data limitations and uncertainties associated with dislodgeable studies that may underestimate the residue include:

1. The California Roller technique, published in OPPTS Guideline 875.2300 - Indoor Surface Residue Dissipation, was utilized to collect dislodgeable residue samples. The California roller was historically developed for the sampling of hard surfaces and turf. There is not sufficient information available to support that the results of the California roller method are statistically comparable to what would have been obtained had the preferred CPSC (Consumer Product Safety Commission) wipe method been utilized for this study.
    - For purposes of collecting residues from pressure treated wood, the Agency typically requires registrants to utilize the CPSC protocol that was developed for collecting residues from CCA pressure treated wood. The CPSC protocol was developed based on extensive background research of various parameters (i.e. number of passes, weight of sampling object, wetting agent, type of sampling material, surface area, and etc.) and can be viewed at http://www.epa.gov/pesticides/factsheets/cca_wood_protocol.pdf. This protocol has been reviewed by the Scientific Advisory Panel (SAP) and was also used to collect residues for examining the impact of sealants on available CCA dislodgeable residues by EPA/ORD.
    - A **stationary cloth** was utilized for all of the DCOIT data collection. In the CPSC protocol, the wipe is physically moved across the wood surface and then rotated 90 degrees and moved again. The use of a stationary cloth does not simulate a wiping motion which may remove more residues via physical or mechanical movement and may be one reason why the reported DCOIT values in this study were quite small.
    - The **surface area** in the CPSC protocol was approximately 400 cm^2 and the surface area sampled in the original DCOIT studies were approximately half the size at 210 cm^2. For the supplementary DCOIT study, the surface area was even less, at 184 cm^2. CPSC analyzed the impact of surface area on residual measurements, and concluded that the greater number of untouched area that is contacted, the amount of residue tended to approach a "maximum" level[1].
    - The **weight of the roller** was heavier than the weight of the block (almost 12 times greater). There is not enough information available to determine whether or not this significantly impacted the results to overcome the other aspects of the study that may underestimate the residues.

The reader is referred to EPA's "***Revised*** *Comprehensive Data Evaluation Record of the Determination of Dislodgeable Residue (DLR) from Scots Pine (MRID #'s 467807-11 & 470040-03) and Southern Yellow Pine (MRID #'s 467807-25 & 470040-04), in Which Both Species Were Treated With RH-287 and Sampled With Either a Wet or Dry*

[1] "Determination of Dislodgeable Arsenic Transfer to Human Hands and Surrogates from CCA-Treated wood." Memorandum from Treye A. Thomas to Patricia M. Bittner. United States Product Safety Commission (1/23/03)

Wipe" dated April 25, 2007 and "*Response to Supplemental Studies Provided by Rohm & Haas to Support the New Registration of Kathon 287 WT Wood Preservative (707-GNT)"* dated June 21, 2007 for a complete discussion on all of the limitations and uncertainties associated with the dislodgeable studies. In order to obtain a more accurate estimate of residential post application exposures and risks, RASSB would recommend that an additional dislodgeable study be conducted to address the uncertainties outlined in the previously mentioned memo.

3.0. Background

AD's Regulatory Management Branch I, received an application from Rhom and Haas Company for registration of Kathon 287 containing 25% DCOIT as the active ingredient. Kathon 287 is an end use product used as a pressure treated wood preservative. DCOIT is currently registered for use in antifoulant paint products.

4.0. Product Use Profile

Kathon 287 is an end-use product that is to be used as a wood preservative to protect treated wood articles from fungi, mold, and mildew. Kathon 287 is a liquid containing 25% DCOIT and is intended to be used at an application rate of 500 to 1600 ppm ai solution in the pressure treatment of above ground and in-ground wood applications such as decking, fencing and fence posts, rails, spindles, flooring, trellises, gazebos, and wood shingles. Additionally, Kathon 287 may also be applied at an application rate of 400 to 1200 ppm ai solution in the pressure treatment of millwork and joinery, trim and facia, and sill plates. A retention rate of 0.0125 to 0.065 pounds ai/cubic foot (pcf) is required for all the wood treatment uses. At this time, Kathon 287 cannot be used to treat wood intended for direct continuous salt water or freshwater immersion and must not be used for packaging food or feed or in the manufacture of bee hives.

Kathon 387 will be used in a two-part system. Pack 1 (EcoVance) of the system contains 25% DCOIT while Pack 2 (PolyVance) is a mixture of an acrylic polymer, surfactant, and defoamer. EcoVance and PolyVance will be shipped together in separate containers to the customer along with mixing and application instructions. The customer will prepare the treatment solution by mixing, by weight, 2.5 parts PolyVance with 1 part EcoVance, then diluting with water until the desired concentration is achieved.

5.0. Selection of Toxicological Endpoints for the Non-dietary Assessment

A complete discussion of the endpoints selected for use in the risk assessments can be found in the following memo: "*4,5-dichloro-2-n-octyl-3(2H) isothiazolone [C9211; RH-287] - Revised* Endpoint Selection Report by the Antimicrobials Division Toxicity Endpoint Selection Committee (ADTC)" (May 10, 2007). A summary of the toxicity endpoints used in this assessment is provided in Table 1.

Table 1. Summary of Toxicological Doses and Endpoints for RH-287			
Exposure Scenario	**Dose Used in Risk Assessment (mg/kg/day)**	**Target MOE and UF for Risk Assessment**	**Study and Toxicological Effects**
Dietary Risk Assessments			
Acute Dietary (females 13-49)	**NOAEL** = 30 mg/kg/day	**FQPA SF = 10** **UF = 100** (10x inter-species extrapolation, 10x intra-species variation) **Acute RfD (aPAD)** = 0.03 mg/kg/day	Developmental toxicity study-Rat (MRID 43471604) LOAEL = 100 mg/kg/day based on increased incidence of wavy ribs.
Acute Dietary (general population)	**NOAEL** = 30 mg/kg/day	**FQPA SF = 10** **UF = 100** (10x inter-species extrapolation, 10x intra-species variation) **Acute RfD (aPAD)** = 0.03 mg/kg/day	Developmental toxicity study-Rat (MRID 43471604) LOAEL = 100 mg/kg/day based on increased incidence of wavy ribs.
Chronic Dietary (all populations)	**NOAEL** = 30 mg/kg/day	**FQPA SF** = **10** **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **Chronic RfD (cPAD)** = 0.03 mg/kg/day	Reproduction toxicity study – Rat (MRID 45756501) Parental LOAEL = 62 mg/kg/day (M); 67 mg/kg/day (F), based on decreased body weight gain in males and females.
Non-Dietary Risk Assessments			
Incidental Oral Short-Term (1-30 days) Intermediate-term (30-days – 6months)	**NOAEL (offspring)** = 16 mg/kg/day	**Target MOE** = **100** (10x inter-species extrapolation, 10x intra-species variation)	Reproduction toxicity study – Rat (MRID 45756501) Offspring LOAEL = 30 (M) and 33(F) mg/kg/day, based on decreased spleen and thymus weights.
Dermal Short-Term (1 to 30 days) and Intermediate-term (30 days- 6 months)	**LOAEL** = 32 µg/cm^2	**Target MOE** = **100** (10x inter-species extrapolation, 3x intra-species variation, 3x for lack of derived 10% response level)	Dermal sensitization study – guinea pigs (MRID 47004002) LOAEL = 32 µg/cm^2 based on positive dermal sensitization response.

Table 1. Summary of Toxicological Doses and Endpoints for RH-287			
Exposure Scenario	**Dose Used in Risk Assessment (mg/kg/day)**	**Target MOE and UF for Risk Assessment**	**Study and Toxicological Effects**
Dermal Long-Term (>6 months)[a]	**NOAEL** = 20 mg/kg/day	**Target MOE = 300** (10x inter-species extrapolation, 10x intra-species variation; 3x for lack of chronic study)	28-day oral toxicity study in the rat MRID 42214903 LOAEL(systemic) = 100 mg/kg/day, based on alterations in hematology, clinical chemistry, and microscopic lesions of the stomach
Inhalation (all durations)	**HEC** [b] = 0.0024 mg/m^3	**Target MOE = 30**	90-day Inhalation toxicity study –rat (MRID 43487501) NOAEL = 0.02 mg/m^3 LOAEL = 0.63 mg/m^3, based on histopathological alterations of the nose, lung, and larynx.
Cancer	not formally classified as to carcinogenicity. No carcinogenicity data available.		

[a]Based on the use of an oral endpoint for dermal risk assessments, the dermal absorption value of 50% will be used in dermal risk assessments.
[B] Based on calculating the Regional Deposited Dose Ratio (RDDR) for nonhygroscopic particles from the 90-day rat study

6.0. Human Exposure Assessment

Based on the use pattern specified on the Kathon 287 label, RASSB has determined that there is a potential for dermal and inhalation exposures to pressure treatment facility workers associated with the active ingredient, DCOIT. Furthermore, there is a potential for residential post-application exposure to children playing on decks and playground equipment made with Kathon 287 treated wood. Table 2 presents the DCOIT exposure scenarios assessed in this document.

Table 2. Exposure Scenarios Associated with Occupational and Residential Exposures to DCOIT			
Method of Application	Exposure Scenario	Route of Exposure	Application Rate
Use Site Category: X – Wood Preservative			
Pressure treated wood preservative	Occupational: • Pressure treatment facility worker daily functions	LT Dermal and ST/IT/LT inhalation	1600 ppm ai (final treatment solution)
	Occupational: • Construction operations (cutting, sanding, sawing, etc.)	ST/IT/LT inhalation of wood dust	1600 ppm ai (final treatment solution)
	Residential: • Child playing on decks and play sets	ST/IT Dermal and incidental oral	1600 ppm ai (final treatment solution)

ST= short-term (1 to 30 days), IT=intermediate-term (1 to 6 months), LT= long-term (>6 months)

6.1 Occupational Handler Exposures and Risks for DCOIT as formulated in Kathon 287 Pressure Treatment Wood Preservative

Since no chemical specific residue data or exposure studies were submitted to support this DCOIT registration application, AD used proprietary surrogate unit exposure data and maximum application rates from labels to determine dermal and inhalation exposures and risks for occupational handler scenarios pertaining to DCOIT wood preservative listed in Table 2.

6.1.1 Inhalation Exposure and Risks

There is the potential for inhalation exposure to occupational handlers at pressure treatment facilities. In addition, potential inhalation exposure and risks to wood dust containing DCOIT are also presented.

6.1.1.1 Pressure Treatment Facilities

To determine worker inhalation exposures at pressure treatment facilities AD used Forest Products Research Laboratory's (FPRL) proprietary CCA hexavalent chromium inhalation study as a surrogate for DCOIT exposures (FPRL 2005, MRID 467208-01, USEPA 2006). This CCA study was conducted to estimate the potential worker inhalation exposure to Cr^{+6} at three treatment facilities in the Unites States treating dimensional lumber, plywood, and poles. The commercial facilities were located in Rainier, OR; Savannah, GA; and Tampa, FL. Each site had a unique layout, but all sites used similar CCA pressure treatment processes. The wood at each facility was treated at nominal retention rates of 0.25 to 2.5 pounds per cubic foot (pcf). Specific information for each site is provided in Table 3.

Table 3. FPRL Study Site Parameters			
Parameter	Rainier, OR	Savannah, GA	Tampa, FL
Treatment-related Parameters			
Number and type of cylinders	3 cylinders: 1 @ 6½' x 82' 1 @ 6' x 80' 1 @ 6' x 62' (used exclusively for CCA)	3 cylinders: 1 out of service 2 @ 6' x 60' newer one used exclusively for borate other one used exclusively for CCA	4 cylinders 1 @ 6' x 86' (utilize copper azole preservative) 2 @ 6' x 82' (one dedicated to CCA 1 @ 6' x 80' (utilize copper azole preservative)
CCA articles treated during study	Plywood and 6 x 6 lumber	Mostly 0.25 pcf retention plywood 0.4 pcf cross arms (for utility poles) 10' x 12' beams	0.4 pcf retention fence posts 2.5 pcf poles for marine applications (primary articles treated) 0.6 pcf poles for near salt water application 0.25 pcf plywood
Type of plant (i.e. pressure treatment capacity)	Automated[a]	Manual[b]	Automatic[a]
Rail bridge (connects track on pad with tracks into cylinder)	Pneumatic rail bridge with expanded metal walking surface lowered in place	2 single rails put in place by worker; glove use inconsistent	2 single rails put in place by worker; glove use inconsistent
Cylinder door	Closed/opened manually, sealed pneumatically	Left open from last charge Closed/opened/sealed manually	Left open from last charge Closed/opened manually, sealed pneumatically Due to sump/door configuration, worker must open door in front of him and cross through the mist escaping from cylinder
Ventilation system	Local exhaust canopy above all 3 cylinder doors	None mentioned	None mentioned
Relative wind direction	Workers generally upwind of cylinders	Not specified in relationship to workers	Workers generally upwind of cylinders
Removal of debris from cylinder	After completion of cycle: worker uses hose to spray off excess solution and debris from bottom of cylinder	After completion of cycle: worker uses hose to spray off excess solution and debris from bottom of cylinder	Before cycle: worker uses piece of wood or metal to scrape out debris at bottom of cylinder and in lower lip of door
Sampling/study-related Parameters			
Sampling dates	September 12 - 16	October 10 - 14	November 7 – 11

Table 3. FPRL Study Site Parameters			
Parameter	Rainier, OR	Savannah, GA	Tampa, FL
Number of test days [c]	5[c]	5	5
No. of charges monitored	16	17	32
Total cubic feet of wood treated over study duration	5,414	6,870	18,790
Total pounds of Chromic acid absorbed over study duration[d]	1,339	1,455	8,065
Average lbs of CrO_3 absorbed during a monitoring period	117	280	877
Mean charge duration	3.7 hours	0.75 hours[e]	1 hour
Mean retention (pcf)	0.58	0.48	0.95

a. Automatic = duration of the treatment cycles and the concentration of the preservative to be pumped into the cylinders are determined by operations software from input parameters. The treatment cycles advance automatically and operations can be monitored from an enclosed operations area above the cylinders.
b. Manual = Treatment operation valves are opened and closed by the Treatment Operator
c. At the Rainier site, three shifts were monitored: day, swing, and overnight. The study team members left workers unattended from midnight to 7:00 AM.
d. Report lists this as total pounds of chromic acid absorbed, but states that the form of chromium in chromic acid is hexavalent. Chromic acid is 47.5% of CCA by weight.
e. Study report states that this value is estimated because not all charge durations were reported.

A variety of tasks were monitored at each site. Even though many of the tasks overlapped job functions, the worker replicates were assigned as follows: treatment operator (TO), treatment assistant (TA), forklift operator (FO), packer (PK), tagger (TG), supervisor (SU), and test borer (TB). The number of replicates for each job function monitored included 18 treatment operators, 22 treatment assistants, 8 packers, 15 supervisors, 12 forklift operators, 10 taggers, and 7 test borers. The duration of inhalation monitoring was approximately 6 working hours per replicate. Table 4 provides the responsibilities performed for each job function monitored. The reader is referred to EPA's original memos for further detailed information on the monitoring methodology, analytical analyses, and resulting surrogate air concentration data observed in the study (USEPA 2006 and 2007).

Table 4. Job functions And Responsibilities At Each Of The Facilities			
Job function	Responsibilities at each site		
	Rainier, OR	Savannah, GA	Tampa, FL
Treatment Operator	Responsible for monitoring treatment cycle of wood, mixing treatment chemicals, and loading and unloading charges of work from treatment cylinder		
	Workers performed tasks largely on the drip pad, including chaining and unchaining charges, opening and closing cylinder door, and moving wood to and from the tracks with a forklift. Workers also performed tasks of Test Borer, taking core samples from treated wood		Worker remained within the enclosed treatment office overlooking drip pad, with occasional visits to the drip pad to communicate with workers and perform wood counts
Treatment Assistant	Workers performed tasks largely on the drip pad, including chaining and unchaining charges, opening and closing cylinder door, and moving wood to and from the tracks with a forklift.		
	Workers were also observed performing post-treatment tasks such as packaging, banding and tagging wood		No additional details provided
Forklift Operator	Workers in several job functions were observed operating forklifts, however, at the Savannah and Tampa sites, some individuals spent more time than others so that a separate job function was created. Workers loaded/unloaded trams before and after treatment, stacked wood in storage, and loaded/unloaded wood on trucks for shipping/receiving		
	Forklifts capable of having an enclosed cab, but side doors were always observed open	Open air cabs	Open air cabs
Packager	Workers observed performing post-treatment tasks, such as tagging, banding, packaging treated wood, moving stacks of wood with a forklift. Activities took place on treatment floor, adjacent to cylinder tracks. Workers performed other tasks such as sweeping/cleaning cylinder tracks.		
	Had workers dedicated to packager job function	No additional details provided	No additional details provided
Tagger	Workers applied plastic tags with manual or pneumatic staplers to ends of treated wood		
	No additional details provided	Temporary workers hired to fill 5 full-time shifts	One workers performed full-time for the monitoring week
Supervisor	Workers spent a portion of time on treatment floor supervising workers.		
	Supervisor also performed forklift duties all over the plant	Members of study team acted as supervisor; spent time in main office and in treatment area	Supervisor spent considerable amount of time away from treatment area and when in area, was typically in treatment office overlooking drip pad
Test Borer	Workers collected all test boring samples, performed analyses and collected CCA work tank samples		
	No additional details provided	No additional details provided	Has workers dedicated to this job function

The volume of wood treated for industrial and residential uses has been estimated from Micklewright (1998). A total of 200 water-based treatment plants responded to this survey. According to this report, 372,100,000 ft^3 of wood is treated via water-based preservatives annually. Based on these data, it is estimated that 6,000 ft^3 of wood on average are treated daily per facility (i.e., (372,100,000 ft^3 / 200 plants) / 310 days of operation per year). The volumes of wood treated are used to estimate the amount of DCOIT used per work shift to extrapolate the air concentration for an unrestricted use assuming a large potion of the treated wood market would use this product (i.e., including residential). The average volume of wood represents the following amount of DCOIT used per work shift:

- Unrestricted Use = 6,000 ft^3 wood x 0.0125 pcf Kathon 287 ai= 75 lbs DCOIT.
- Unrestricted Use = 6,000 ft^3 wood x 0.065 pcf Kathon 287 ai = 390 lbs DCOIT

The surrogate air concentration data from the FPRL study and estimate of quantity of wood treated per work shift were used to calculate DCOIT inhalation exposures which are provided in Table 5. Some of the exposures for individual work tasks at specific facilities and maximum retention rates resulted in MOEs below the Target MOE of 30. Even when the MOEs for theses individual work tasks were averaged across facilities some of them still remained below the Target MOE of 30. The average MOEs are provided in Table 6.

Table 5. Pressure Treatment Facility Worker Inhalation Exposures and MOEs

Job Function	Surrogate Air Conc. (ng/m^3/lb ai)[a]	Amount Handled[b]		Inhalation Exposure (ng/m^3)[c]		Inhalation MOEs[d] (Target MOE = 30)	
		lb ai	lb ai	Min	Max	Min	max
Rainier, OR Site							
TO	0.62	75	390	46.5	241.8	52	**10**
TA	0.54	75	390	40.5	210.6	59	**11**
PK	0.29	75	390	21.75	113.1	110	**21**
SU	0.19	75	390	14.25	74.1	170	32
Savannah, GA Site							
TO	0.6	75	390	45	234	53	**10**
TA	0.25	75	390	18.75	97.5	130	**25**
SU	0.074	75	390	5.55	28.86	430	83
FL	0.087	75	390	6.53	33.93	370	71
TG	0.054	75	390	4.05	21.06	590	110
Tampa, FL Site							
TO	0.12	75	390	9.0	46.8	270	51
TA	0.13	75	390	9.75	50.7	250	47
SU	0.12	75	390	9.0	46.8	270	51
FL	0.36	75	390	27.0	140.4	89	17
TG	0.047	75	390	3.53	18.33	680	130
TB	0.17	75	390	12.8	66.3	190	36

[a] Surrogate air concentration data from the proprietary FPRL study
[b] Amount handled is based on estimate of amounts wood treated per work shift
[c] Inhalation Exposure (ng/m^3) = surrogate air conc (ng/m^3/lb ai) x amt handled (lb ai)
[d] Inhalation MOE = Inhalation HEC (2,400 ng/m^3) / Exposure (ng/m^3) where Target MOE = 30

Table 6. Average MOEs Across Pressure Treatment Facilities

Job Function	Average MOE at Min Retention Rate	Average MOE at Max Retention Rate
TO***	120	**24**
TA***	140	**28**
PK*	110	**21**
SU***	290	56
FL**	230	44
TG**	640	120
TB*	190	36

* No Average, job function is observed at only 1 facility in the study

** Average MOE taken from 2 facilities

*** Average MOE taken from 3 facilities

6.1.1.2 Wood Dust Exposure and Risk Estimates

There is a potential for workers in construction facilities to be exposed to treated wood dust during typical cutting and sanding operations. Rhom and Hass has submitted a DCOIT-Treated Wood Dust Exposure Assessment that utilized results from a wood leach study to represent bioavailability of DCOIT from the wood dust matrix. Based on conversations with expert inhalation toxicologists, AD believes that utilizing the bioavailability factor is reasonable.

To determine the leaching potential of DCOIT in wood dust, the AWPA E11-97 was used. Wood cubes treated with EcoVance-PolyVance formulations at a DCOIT concentration of 1600 ppm (or 1600 ng DCOIT/mg wood) were placed in a beaker and vacuum impregnated with water for 1 hour. The water level was then increased to 300 gm and the cubes remained in the water for a total 6 hours. After 6 hours of continuous contact with water, the water was analyzed for DCOIT. The results showed that 0.5% of the total DCOIT leached into the water. AD agreed with Rhom and Haas's assumption that all the DCOIT that leached out of the wood into the water over the first 6 hours of immersion is biologically available upon inhalation of the wood dust into the respiratory tract. Any remaining DCOIT in the wood is considered bound to the wood and is biologically unavailable because of the rapid mucociliary tracheal and nasal clearance. However, the results from this study can not be used in this assessment for the following reasons:

- A complete report containing detailed methodology, data validation, raw data, etc. was not submitted,

- The number of samples is unknown – it appears that only one sample was conducted. The study needs to be conducted on a statistically adequate number of samples, and
- The analyses should be conducted on saw dust rather than cubes. Because of the differences in the volume to surface area ratio, it is expected that there would be a higher leaching potential from saw dust than cubes.

Based on the concentration in the wood, bioavilabilty potential (100% default) and OSHA PEL, inhalation exposure and risk estimates for occupational workers exposed to wood dust from DCOIT-treated wood indoors have been estimated (e.g., manufacturing outdoor furniture with DCOIT-treated wood). OSHA has set the following PELs for wood dust related exposures: 15 mg/m^3 for total wood dust and 5 mg/m^3 for respirable wood dust. EPA used the total wood dust PEL as the upper bound exposure estimate because the toxicity endpoint was based on nasal effects. It is believed that any wood dust concentrations in the air exceeding this PEL will be mitigated by the industry. If it was deemed necessary to characterize the upper bound exposure estimate, EPA could review the monitoring data for wood dust in OSHA's Integrated Management Information System (IMIS). The PEL cited for wood dust is for the wood dust itself, not chemical treatments within the wood dust. Inhalation exposure estimates to DCOIT-treated wood is based on the following equation:

Total wood dust (OSHA PEL 15 mg wood/m^3) x App Rate (ng ai/mg wood) x Bio Factor (100 %) = Inhal Exp (ng/m^3)

Table 7 presents the inhalation exposure and risks for workers in construction facilities. The MOEs are well below the Target MOE of 30. These MOEs can be refined by utilizing a leaching study that corrects the deficiencies as noted in the current study submitted by Rhom and Haas. As an illustration for the need to refine the leaching study, EPA estimated the inhalation exposures using the submitted leaching study. The results show (Table 8) that the MOE at the minimum application rate is above the Target 30. However, AD can not rely on the submitted study because it is likely that the results are underestimated as previously discussed.

Residential inhalation risks to wood dust are believed to be less than that for occupational workers because of the intermittent residential use and most residential uses would be in ambient conditions.

Table 7. Inhalation Exposures and MOE for Workers in Construction Facilities Using 100% Bioavailability		
	Total Wood	
	Min rate	Max rate
Application rate (ng ai/mg wood)	400	1600
Bioavailability (%)	100%	100%
OSHA PEL (mg wood/m3)	15	15
Inhalation exposure (ng ai/m3)	6,000	24000
Inhalation NOAEL (mg/m3)	0.0024	0.0024
Inhalation NOAEL (ng/m3)	2,400	2,400
MOE	**< 1**	**< 1**
Target MOE	30	30

Table 8. Inhalation Exposures and MOE for Workers in Construction Facilities Using 0.5% Bioavailability		
	Total Wood	
	Min rate	Max rate
Application rate (ng ai/mg wood)	400	1600
Bioavailability (%)	0.5%	0.5%
OSHA PEL (mg wood/m3)	15	15
Inhalation exposure (ng ai/m3)	30	120
Inhalation NOAEL (mg/m3)	0.0024	0.0024
Inhalation NOAEL (ng/m3)	2,400	2,400
MOE	80	**20**
Target MOE	30	30

6.1.2 Dermal Exposure and Risks in Pressure Treatment Facilities

There is the potential for dermal exposure to occupational handlers at pressure treatment facilities. It should be noted that short- and intermediate-term dermal exposures were not assessed for the occupational handler because the endpoint is based on dermal sensitization. Instead, dermal sensitization exposures need to be mitigated using personal protective equipment requirements. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed during application will be a long-sleeve shirt, long pants, shoes, socks and chemical-resistant gloves. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential.

DCOIT-specific dermal exposure data are not available therefore, this assessment relies on surrogate CCA data. Long-term dermal exposures for pressure treatment uses are derived from information in the proprietary exposure study entitled "*Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure Treatment of Wood with Arsenical Wood Products"* (ACC, 2002). The CCA study is the only pressure treatment data available (water based solution) to estimate exposure to DCOIT because of similar use scenarios.

The CCA study measured both handlers and post application activities. Although there is overlap in job functions, the handlers are defined as the treating operators (TO) and treating assistants (TA). Three sites were monitored in the CCA study: site A South Carolina, site B Ontario, and site C Oregon. The TO were monitored at Sites A, B, C using 5 replicates at each site. The TA were monitored at Sites A and C using 5 replicates at each site. The post application activities included: tram setter (TS) at Site A (n=5); stacker operator (SO) at Site A (n=4); loader operator (LO) at Sites A, B, C (n=15); supervisor (S) at Site B (n=5); test borer (TB) at Site C (n=5); and the tallyman (TM) at Site C (n=5). According to the CCA study, workers wore cotton long-sleeved shirt and cotton trousers (or one-piece cotton coveralls) over the whole-body dosimeters (*"plus additional shirts or jackets per typical practice at Site B"*) and chemical-resistant or work gloves when appropriate. Thus the estimated risks for DCOIT using the CCA data as surrogate represent maximum PPE (excluding respirators). For the DCOIT assessment, the TO and TA handlers are assessed separately and all of the post application job functions are assessed together.

The measured CCA dermal exposure values were normalized by the treatment solution concentration used at each of the 3 facilities (i.e., unit exposure reported as µg ai/ppm treatment solution). The normalization by treatment solution concentration was performed to extrapolate the measured exposures in the CCA study (monitored at ~0.5% solution) to the amount of DCOIT in the treatment solution concentrations proposed on the Kathon 287 label (i.e., 0.16 to 0.64%). Table 9 presents the dermal unit exposure values normalized to the treatment solution concentration in ppm for (1) all sites, (2) treatment operator (TA handler), (3) treatment assistant (TA handler), and (4) all post application job functions (TS, SO, LO, S, TB, TM).

The U.S. and Canadian sites indicate a difference in the mean dermal exposures. Upon further analysis by Health Canada it was determined that the final vacuum for the pressure treatment process was not performed at site B. The final vacuum is used to remove excess treatment solution. The final vacuum process was performed for 1 to 5 hours at site A and 2 to 3 hours at site C. It is recommended that the final vacuum process according to the AWPA standard be required on the label because it reduces the potential for dermal exposures.

Table 9. Pressure Treatment Unit Exposures (CCA Data as Surrogate for DCOIT)				
Site	Treatment Solution		Statistic	Dermal UE (µg /ppm ai)
	%	ppm		
All sites - Handler Treatment Operator (n = 15)	0.438 to 0.595	4380 to 5950	Average ± std	2.04 ± 2.68
			Median	0.37
			90th percentile	5.39
			Maximum	7.74
US sites - Handler Treatment Operator (n = 10)	0.544 and 0.595	5440 and 5950	Average ± std	0.27 ± 0.16
			Median	0.23
			90th percentile	0.45
			Maximum	0.60
Canadian site - Handler Treatment Operator (n = 5)	0.438	4380	Average ± std	5.6 ± 1.2
			Median	5.2
			90th percentile	6.9
			Maximum	7.7
US sites - Handler Treatment Assistant (n = 10)	0.544 and 0.595	5440 and 5950	Average ± std	0.24 ± 0.14
			Median	0.23
			90th percentile	0.40
			Maximum	0.52
Canadian site - Handler Treatment Assistant (n = 0)	The treatment assistant (TA) was not monitored at site B			
All sites - Postapplication All job functions (TS, SO, LO, S, TB, TM) (n = 39)	0.438 to 0.595	4380 to 5950	Average ± std	0.74 ± 0.73
			Median	0.42
			90th percentile	1.81
			Maximum	3.11
US sites - Postapplication All job functions (TS, SO, LO, TB, TM) (n = 29)	0.544 and 0.595	5440 and 5950	Average ± std	0.49 ± 0.51
			Median	0.35
			90th percentile	1.2
			Maximum	2.0

Table 9. Pressure Treatment Unit Exposures (CCA Data as Surrogate for DCOIT)				
Canadian sites - Postapplication All job functions (LO and S) (n = 10)	0.438	4380	Average ± std	1.5 ± 0.80
			Median	1.4
			90th percentile	2.2
			Maximum	3.1

ppm = (% treatment solution) * (10,000)
Air concentration was calculated as µg collected per sample per ppm / (480 min per day x 2 L/min)

DCOIT dermal handler exposures and risks can be estimated using the CCA unit exposures presented in Table 9 above. The CCA handler job functions of treating operator (TO) and treating assistant (TA) are used as a surrogate for the pressure treatment operators at DCOIT treatment facilities. The normalized unit exposures (µg/ppm treatment solution) are extrapolated to the proposed label DCOIT treatment solution concentrations (400 to 1600 ppm ai). This DCOIT assessment estimated TO and TA dermal risks at the US sites (final vacuum process) and Canadian site (no final vacuum) and are presented in Table 10. It is recommended that the final vacuum process be required on the label because it reduces the exposure/risks as indicated in Table 10.

Table 10. Long-term Dermal Exposures and Risks for DCOIT Pressure Treatment Facility Workers							
Job	**Dermal UE**	**Application rate (ppm ai)**		**Dermal Dose (mg/kg/day) [a]**		**LT Dermal MOE[b] Target MOE = 300**	
	(µg/ppm ai)	**Min.**	**Max.**	**Min.**	**Max.**	**Min**	**Max**
US Sites (Sites A and C) - with Final Vacuum							
TO	0.27	400	1600	0.00077	0.0031	26,000	6,500
TA	0.24	400	1600	0.00069	0.0027	29,000	7,300
Canadian Site (Site B) - without Final Vacuum							
TO	5.6	400	1600	0.01600	0.0640	1,300	310
TA	The treatment assistant was not monitored at site B						

[a] Dermal dose (mg/kg/day) = UE (µg/ppm ai) x App Rate (ppm ai) x 0.001 mg/µg x 50% dermal abs x 1/70 kg

[b] LT Dermal MOE = Dermal NOAEL (20 mg/kg/day) / Dermal Dose (mg/kg/day)

6.2 Residential Post-application Exposures to DCOIT treated Wood

There is a potential for post-application DCOIT exposures to occur to children playing on treated decks and play sets. These exposures include ST dermal and ST incidental oral exposures. These exposures and corresponding MOEs are estimated below.

6.2.1 Dermal Exposure

Potential dermal exposure of children can result while playing on DCOIT-treated structures such as decks and/or play sets. A deterministic assessment has been developed by EPA to assess children's exposure using the 24-hr dislodgeable residue value. The reader is referred to the EPA review "***Revised*** *Comprehensive Data Evaluation Record of the Determination of Dislodgeable Residue (DLR) from Scots Pine (MRID #'s 467807-11 & 470040-03) and Southern Yellow Pine (MRID #'s 467807-25 & 470040-04), in Which Both Species Were Treated With RH-287 and Sampled With Either a Wet or Dry Wipe*" dated April 25, 2007 and "*Response to Supplemental Studies Provided by Rohm & Haas to Support the New Registration of Kathon 287 WT Wood Preservative (707-GNT)"* dated June 21, 2007 for a complete review of the DCOIT dislodgeable studies.

Because the dermal toxicological endpoint is based on the sensitization effect, the maximum DCOIT residue dislodged from the wood can be directly compared to the endpoint to estimate risk or MOE because both factors are in terms of the same units. The short-term dermal MOE is estimate using the following equation:

ST Dermal MOE = ST Dermal NOAEL ($\mu g/cm^2$) / Dermal Exposure ($\mu g/cm^2$)

where,

ST Dermal NOAEL = 32 $\mu g/cm^2$

Dermal Exposure ($\mu g/cm^2$) = Maximum DCOIT Dislodgeable residue of 0.131 $\mu g/cm^2$

ST Dermal MOE = 240

Although the ST-dermal MOE is above the Target MOE of 100, RASSB believes that the residential post-application exposures may be underestimated using the current dislodgeable data due to the uncertainties and limitations of the studies. The major data limitations and uncertainties associated with dislodgeable studies include:

1. The California Roller technique, published in OPPTS Guideline 875.2300 - Indoor Surface Residue Dissipation, was utilized to collect dislodgeable residue samples. The California roller was historically developed for the sampling of hard surfaces and turf. There is not sufficient information available to support that the results of the California roller method are statistically comparable to what would have been obtained had the preferred CPSC (Consumer Product Safety Commission) wipe method been utilized for this study.
    - For purposes of collecting residues from pressure treated wood, the Agency typically requires registrants to utilize the CPSC protocol that was developed for collecting residues from CCA pressure treated wood. The CPSC protocol was developed based on extensive background research of various parameters (i.e. number of passes, weight of sampling object, wetting agent, type of sampling material, surface area, and etc.) and can be viewed at http://www.epa.gov/pesticides/factsheets/cca_wood_protocol.pdf. This

protocol has been reviewed by the Scientific Advisory Panel (SAP) and was also used to collect residues for examining the impact of sealants on available CCA dislodgeable residues by EPA/ORD.

- A **stationary cloth** was utilized for all of the DCOIT data collection. In the CPSC protocol, the wipe is physically moved across the wood surface and then rotated 90 degrees and moved again. The use of a stationary cloth does not simulate a wiping motion which may remove more residues via physical or mechanical movement and may be one reason why the reported DCOIT values in this study were quite small.
- The **surface area** in the CPSC protocol was 400 cm^2 and the surface area sampled in the original DCOIT studies were approximately half the size at 210 cm^2. For the supplementary DCOIT study, the surface area was even less, at 184 cm^2. CPSC analyzed the impact of surface area on residual measurements, and concluded that the greater number of untouched area that is contacted, the amount of residue tended to approach a "maximum" level[2].
- The **weight of the roller** was heavier than the weight of the block (almost 12 times greater). There is not enough information available to determine whether or not this significantly impacted the results.

2. The Southern Yellow Pine residues at day 7 in the original study (25.43 ± 6.77 ng/cm^2) are greater than the Southern Yellow Pine residues reported in the supplementary study (18 ± 3 ng/cm^2). This may be a function of the retention rates utilized (0.070 pcf and 0.049 pcf respectively); however there is no scientific data available to draw conclusions on the relationship between retention rates and dislodgeable residues.
3. The retention rate range that is listed on the label is 0.0125 pcf – 0.064 pcf. The maximum retention rate that was utilized for collecting residues from SYP at 24 hours after treatment was 0.049 pcf. This data has been extrapolated by EPA in attempt to estimate 24 hour residues for a retention rate of 0.064 pcf. However, due to this extrapolation, there is the potential that the calculated residual values may inaccurate.
4. The retention rates identified for the original study were calculated based on the initial and final mass of the wood specimens. The retention rate in the supplementary study was calculated based on AWPA's Book of Standards, procedure A30-00 in which the DCOIT level was obtained by drilling a 0.25 inch hole 0.6 inches deep using a Forstner bit. It is difficult to determine if these retention rates are comparable considering that the methodologies are different.
5. In the supplementary study report, the raw data used to calculate the reported values (e.g. correction for fabric blanks, standard curve, chromatograms, etc.) were not provided.
6. Samples were collected in duplicate from 2 different pieces of wood (R-Series and V-Series) per sampling interval. These values were averaged together to calculate the dislodgeable residue for a specific time increment. AD typically

[2] "Determination of Dislodgeable Arsenic Transfer to Human Hands and Surrogates from CCA-Treated wood." Memorandum from Treye A. Thomas to Patricia M. Bittner. United States Product Safety Commission (1/23/03)

requires that samples are collected in triplicate from the same surface type per time period of sampling.

In order to obtain a more accurate estimate of residential post application exposures and risks, RASSB would recommend that an additional dislodgeable study be conducted to address the uncertainties outlined in the dislodgeable residue memos as referenced above.

6.2.2 Incidental Oral Exposure

Potential oral exposure of children can result from hand-to-mouth activities while playing on DCOIT-treated structures such as decks and/or play sets. A deterministic assessment has been developed by EPA to assess children's exposure using the 24-hr DCOIT dislodgeable wood residue value along with exposure algorithms and parameters from the probabilistic Stochastic Human Exposure and Dose Simulation (SHEDS) model (USEPA 2005). SHEDS was developed by EPA to assess exposure to children contacting CCA-treated structures (i.e., decks and play sets). The SHEDS report along with EPA's response to the Science Advisory Panel's (SAP) review comments is located at http://www.epa.gov/heasd/sheds/cca_treated.htm. Since, the incidental oral toxicological endpoints of concern for DCOIT are non cancer, the amortization of exposure over time that is provided in the SHEDS model for CCA is not appropriate for this assessment. The frequency of exposure is believed to be best represented by the short-term duration (i.e., 1 to 30 days of continuous exposure).

The potential daily dose (PDD) from the incidental oral route of exposure is estimated using the following modified equation from the SHEDS report (i.e., SHEDS Appendix 2 page A2-8):

$$PDD = \frac{SR \times SA \times FQ \times ET \times SE \times CF1}{BW}$$

where:

PDD	=	Potential daily dose (mg/kg/day);
SR	=	Wood dislodgeable surface residue (µg/cm^2);
SA	=	Surface area of the hands that contact both the treated area, and the individual's mouth (20 cm^2/event) (USEPA, 2000 and 2001);
FQ	=	Frequency of hand-to-mouth events (mean 8.45 events/hr) (Table 10, page 62, USEPA 2005);
SE	=	Saliva extraction efficiency (50% unitless fraction) (USEPA, 2000 and 2001);
ET	=	Exposure Time (mean 1 hr/day) (Table 49 page165 USEPA 2005);
CF1	=	Unit conversion factor (0.001 mg/µg); and
BW	=	Body weight (15 kg) (USEPA, 2000 and 2001).

Table 11 presents the ST-incidental oral exposures and corresponding MOEs. As previously mentioned, although the ST-incidental oral MOE is above the Target MOE of 100, RASSB believes that the residential post-application exposures may be underestimated using the current dislodgeable data due to the uncertainties and limitations of the studies as discussed above. In order to obtain a more accurate estimate of residential post application exposures and risks, RASSB would recommend that an additional dislodgeable study be conducted to address the uncertainties outlined in the dislodgeable residue memos as referenced above.

Table 11. Incidental Oral Exposure and Risk for Children Playing on DCOIT Treated Decks and Play sets		
Dislodgeable residue (µg/cm^2)	DR	0.131
Body surface area (cm^2)	SA	20
Frequency of hand to mouth (cm^2/event)	FQ	8.45
Exposure time (hr/day)	ET	1
Saliva extraction (%)	SE	50%
Conversion factor (0.001 mg/µg)	CF1	0.001
Body weight (kg)	BW	15
Oral Dose (mg/kg/day)		0.0007
ST Oral NOAEL (mg/kg/day)		16
ST MOE		22,000
Target MOE = 100		

7.0. References

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Sign-off Date : 07/27/07
DP Barcode Nos.: D330114 and D340329